

SUBSTITUTE FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
00786/048005

SERIAL NO.
08/353,508

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use several sheets if necessary)

APPLICANT
Warren M. Zapol

FILING DATE
December 9, 1994

GROUP
3300

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
all	AA	4 2 8 7 0 4 0	09/01/81	Alamaro	204	179	
all	AB	4 3 3 6 7 9 8	06/29/82	Beran	A61N	128	
all	AC	4 8 7 7 5 8 9	10/31/89	O'Hare	422	186.24	
all	AD	4 0 1 0 8 9 7	03/08/77	Treharne et al.	239	8	
all	AE	4 9 1 5 9 1 5	04/10/90	Treharne et al.	422	186.24	
all	AF	4 2 9 7 1 2 3	10/27/81	Wyse et al.	71	58	
all	AG	3 7 8 5 3 7 7	01/15/74	Jorgensen	128	188	
all	AH	4 6 6 7 6 6 8	05/26/87	Wetterlin	128	203.15	
all	AI	4 5 9 2 3 4 8	06/03/86	Waters et al.	128	200.23	
all	AJ	4 5 3 4 3 4 3	08/13/85	Nowacki et al.	128	200.23	
all	AK	4 8 5 2 5 6 1	08/01/89	Sperry	128	200.23	
all	AL	4 9 5 4 5 2 6	9/4/90	Keefer	514	611	
all	AM	5 1 5 5 1 3 7	10/13/92	Keefer et al.	514	611	
all	AN	5 2 0 8 2 3 3	5/4/93	Keefer et al.	514	231.8	

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
all	AO	WO 92/17445	15/10/92	PCT	—	—		
all	AP	WO 93/12068	24/06/93	PCT	—	—		
all	AQ	GB-A-2 144 997	20/03/85	Great Britain	—	—		
	AR	2178958	2/87	Great Britain				
	AS							

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

all	AT	Blomqvist et al., Inhaled Nitric Oxide (NO): A Selective Pulmonary Vasodilator Reversing Human Hypoxic Pulmonary Vasoconstriction (HPV), Circulation 84:361, 1991
all	AU	Desai et al., Involvement of Nitric Oxide in the Reflex Relaxation of the Stomach to Accommodate food or Fluid, Nature 351:477, 1991
all	AV	Donahoe et al., Production of O ₃ , NO, and N ₂ O in a Pulsed Discharge at 1 Atm, Ind. Eng. Chem. 16:208-215, 1977

EXAMINER

Warren M. Zapol

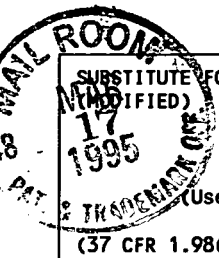
DATE CONSIDERED

3/20/96

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR 1.98(b))				APPLICANT Warren M. Zapol			
				FILING DATE December 9, 1994		GROUP 330	
OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
all	BA		Fractacci et al., Inhaled Nitric Oxide, Anesthesiology 75:990-999, 1991				
all	BB		Pepke-Zaba et al., Inhaled Nitric Oxide as a Cause of Selective Pulmonary Vasodilation in Pulmonary Hypertension, The Lancet 338:1173-1174, 1991				
all	BC		Rimar et al., Prolonged Duration of Inhaled Nitric Oxide Induced Vasodilation in Perfused Rabbit Lungs Circulation 84:362, 1991				
all	BD		Roberts, Jr. et al., Inhaled Nitric Oxide (NO): A Selective Pulmonary Vasodilator for the Treatment of Persistent Pulmonary Hypertension of the Newborn (PPHN), Circulation 84:1279, 1991				
all	BE		Dupuy et al., Bronchodilator Action of Inhaled Nitric Oxide in Guinea Pigs, J. clin. Invest. 90:421-428, 1992				
	BF		Kacmarek et al., Nitric Oxide as a Bronchodilator in Methacholine Induced Bronchospasm in Mild Asthmatics, 1993 ALA/ATS International Conference, May 16-19, 1993, San Francisco, CA #21556 (Abstract)				
	BG		Messent et al., The Pulmonary Physician and Critical Care, Thorax 47:651-656, 1992				
	BH		Swami et al., the Pulmonary Physician and Critical Care, Thorax 47:555-562, 1992				
	BI		Frostell, MD, PhD et al., Inhaled Nitric Oxide: A Selective Pulmonary Vasodilator Reversing Hypoxic Pulmonary Vasoconstriction, Circulation 83:2038-2047, 1991				
all	BJ		Dalby et al., Comparison of Output Particle Size Distributions from Pressurized Aerosols Formulated as Solutions or Suspensions, Pharmac. Re. 5:36-39, 1988				
all	BK		Buga et al., Endothelium-Derived Nitric Oxide Relaxes Nonvascular Smooth Muscle, European J. of Pharmc. 161:61-72, 1989				
all	BL		Ishii et al., A Simple and Sensitive Bioassay Method for Detection of EDRF with RFL-6 Rat Lung Fibroblasts, Am. J. Physiol. 261:H598-H603, 1991				
all	BM		Stuart-Smith et al., Epithelium, contractile Tone, and Responses to Relaxing Agonists in Canine Bronchi, J. Appl. Physiol. 69:678-685, 1990				
all	BN		Suzuki et al., The Relationship Between Tissue Levels of Cyclic GMP and Tracheal Smooth Muscle Relaxation in the Guinea-Pig, Clinical & Pharmacol. & Physiol. 13:39-46, 1986				
EXAMINER			DATE CONSIDERED				
Aaron J. Lee			3/20/96				
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
	CA		Tan et al., Cigarette Smoke Activates Guanylate Cyclase and Increases Guanosine 3', 5' -Monophosphate in Tissues, Science 198:934-936, 1977				
all	CB		Maron et al., Cigarette Smoke Causes Acute Fluctuations in the Cyclic GMP Content of the Isolated Intact Lung, Respiration 43:39-44, 1984				
all	CC		Heaslip et al., Co-Regulation of Tracheal Tone By Cyclic AMP- and Cyclic GMP-Dependent Mechanisms, J. Pharmacol. & Experms. 243:1018-1026, 1987				
	CD		Moncada et al., Nitric Oxide: Physiology, Pathophysiology, and Pharmacology, Pharmacol. Reviews 91:109-141, 1991				
	CE		Kalant et al., Drugs and the Respiratory System, Chapter 39 362-397, 1989				
all	CF		Gilman et al., Vascular Effects of Cigarette Smoke in Isolated Pig Lungs, Am. Rev. Respir. Dis. 124:549-553, 1981				
all	CG		Flenley, Today's Treatment of Airway Obstruction.. and Tomorrow's?, Respiration 55:4-9, 1989				
all	CH		Physician's Desk Reference, pages 969-971, 2322-2323, 668-670				
all	CI		Edwards et al., Activation of Hepatic Guanylate Cyclase by Nitrosyl-Heme Complexes, Biomed. Pharmacol. 30:2531-2538, 1981				
all	CJ		Garg et al., Nitric Oxide Generating Vasodilators Inhibit Mitogenesis and Proliferation of BALB/C 3T3 Fibroblasts by a Cyclic GMP-Independent Mechanism, Biochem. Biophys. Res. Comm. 171:474-479, 1990				
all	CK		Schmidt et al., Stimulation of Soluble Coronary Arterial Guanylate Cyclase by Sin-1, European J. Pharmacol. 122:75-79, 1986				
all	CL		McNamara et al., Adenosine 3', 5' Monophosphate Formation by Preparations of Rat Liver Soluble Guanylate Cyclase.....and Other Nitroso Compounds, Can. J. Physiol. Pharmacol. 58:1446-1456, 1980				
all	CM		Ignarro, Biosynthesis and Metabolism of Endothelium-Derived Nitric Oxide, Annu. Rev. Pharmacol. Toxicol. 30:535-560, 1990				
all	CN		Allen and Hanbury, Product Information Bulletin on Ventolin, 1990				
EXAMINER			DATE CONSIDERED				
Aaron D. Lewis			3/20/96				
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

add	DA	Boje et al., Endothelial Nitric Oxide Generating Enzyme(s) in the Bovine Aorta: Subcellular Location
		Location and Metabolic Characterization, Am. Soc. Pharmacol. & Exper. Therapeutics 253:20-26, 1990
add	DB	Southern et al., Inhibition of Insulin Secretion by Interleukin-1 β and Tumor Necrosis Factor- α via an
		L-Arginine-Dependent Nitric Oxide Generating Mechanism, FEBS 276:42-44, 1990
add	DC	Garg et al., Nitric Oxide-Generating Vasodilators and 8-Bromo-Cyclic Guanosine Monophosphate Inhibit
	Vascular Smooth Muscle Cells, J. Clin. Invest. 83:1774-1777, 1989
duplicate	DD	Garg et al., Nitric Oxide-Generating Vasodilators Inhibit Mitogenesis and Proliferation of BALB/C 3T3
		by a Cyclic GMP-Independent Mechanism, Biochem. Biophys. Res. Comm. 171:474-479, 1990
add	DE	Brune et al., Activation of a Cytosolic ADP-Ribosyltransferase by Nitric Oxide-Generating Agents,
		J. Biol. Chem. 264:8455-8458, 1989
add	DF	Curran et al., Nitric Oxide and Nitric Oxide-Generating Compounds Inhibit Hepatocyte Protein Synthesis,
		FASEB J. 5:2085-2092, 1991
add	DG	Ignarro, Endothelium-Derived Nitric Oxide: Actions and Properties, FASEB J. 3:31-36, 1989
add	DH	Peckham, Physiologic Factors Affecting Pulmonary Artery Pressure in Infants with Persistent Pulmonary
		Hypertension, J. Ped. 6:1005-1010, 1978
add	DI	Zapol et al., Pulmonary Circulation During Adult Respiratory Distress Syndrome, Mercel Dekker,
		241-273, 1985
add	DJ	Fox et al., Pulmonary Hypertension in the Perinatal Aspiration Syndromes, Pediatrics 59:205-211, 1977
add	DK	Dworetz et al., Survival of Infants with Persistent Pulmonary Hypertension without Extracorporeal Membrane
		Oxygenation, Pediatrics 84:1-6, 1989
add	DL	Fishman, Pulmonary Hypertension and Cor Pulmonale, Chapter 64 pp. 999-1048
add	DM	Radermacher et al., Comparison of Ketanserin and Sodium Nitroprusside in Patients with Severe ARDS,
		Anesthesiology 68:152-157, 1988
add	DN	Vlahakes et al., The Pathophysiology of Failure in Acute Right Ventricular Hypertension: Hemodynamic and
		Biochemical Correlations, Circulation 63:87-95, 1981

EXAMINER

Harold J. Lee

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MAR 17 1995 INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		APPLICANT Warren M. Zapol		FILING DATE December 9, 1994		GROUP 3300	
OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
all	EA		Ignarro et al., Endothelium-Derived Relaxing Factor Produced and Released from Artery and Vein is Nitric Oxide, Proc. Natl. Acad. Sci. USA 84:9265-9269, 1987				
all	EB		Palmer et al., Nitric Oxide Release Accounts for the Biological Activity of Endothelium-Derived Relaxing Factor, Nature 327:524-526, 1987				
	EC		Ignarro, Biological Actions and Properties of Endothelium-Derived Nitric Oxide Formed and Released From Artery and Vein, Dept. Pharmacol. pp. 23-278				
all	ED		Higgenbottom et al., Am. Rev. Resp. Dis. Suppl. 137:107, 1988				
all	EE		Zapol et al., Pulmonary Hypertension in Severe Acute Respiratory Failure, N.E. J. Med. 296:476-480, 1977				
all	EF		Meyer et al., Nitric Oxide (NO), a New Test Gas for Study of Alveolar-Capillary Diffusion, Eur. Respir. J. 2:494-496, 1989				
all	EG		Hounam et al., particle Deposition pp. 125-156				
all	EH		Ignarro, Endothelium-Derived Nitric Oxide: Actions and Properties, FASEB J. 3:31-36, 1989				
all	EI		Archer et al., Comparison of the Hemodynamic Effects of Nitric Oxide and Endothelium-Dependent Vasodilators in Intact Lungs, J. Appl. Physiol. 68:735-747, 1990				
all	EJ		Furchgott et al., Endothelium-Derived Relaxing and Contracting Factors, FASEB J. 3:2007-2018, 1989				
all	EK		Archer et al., Hypoxic Pulmonary Vasoconstriction is Enhanced by Inhibition of the Synthesis of an Endothelium Derived Relaxing Factor, Biochem. Biophys. Res. Comm. 164:1198-1205, 1989				
all	EL		Brashers et al., Augmentation of Hypoxic Pulmonary Vasoconstriction in the Isolated Perfused Rat Lung by in Vitro Antagonists of Endothelium-Dependent Relaxation, J. Clin. Invest. 82:1495-1502, 1988				
all	EM		Ignarro et al., Mechanism of Vascular Smooth Muscle Relaxation by Organic Nitrates, Nitrites, Nitroprusside and Nitric Oxide:....S-Nitrosothiols as Active Intermediates, J. Pharmacol. Experm. Ther. 218:739-749, 1981				
all	EN		Kadowitz et al., Pulmonary Vasodilator Responses to Nitroprusside and Nitroglycerin in the Dog, Clin. Invest. 67:393-902, 1981				
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(37 CFR 1.98(b))				FILING DATE December 9, 1994		GROUP 3300	
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ADD	FA		Naeije et al., Effects of vasodilators on Hypoxic Pulmonary Vasoconstriction in Normal Man, Chest 82: 404-410, 1982				
ADD	FB		Flavahan et al., Respiratory Epithelium Inhibits Bronchial Smooth Muscle Tone, J. Appl. Physiol. 58:834-838, 1985				
ADD	FC		Hugod, Effect of Exposure to 43 ppm Nitric Oxide and 3.6 ppm Nitrogen Dioxide on Rabbit Lung, Int. Arch. Occup. Environ. Health 42:159-167, 1979				
ADD	FD		Nakajima et al., Biological Effects of Nitrogen Dioxide and Nitric Oxide, Nitrogen Oxides 121-141				
ADD	FE		Packer, Is It Ethical to Administer Vasodilator Drugs to Patients with Primary Pulmonary Hypertension, Chest 95:1173-1175, 1989				
	FF		Agabwal et al., Nature pp. 915-916, 1965				
ADD	FG		Stavert et al., Nitric Oxide and Nitrogen Dioxide..... Concentrations for Brief Periods, Inhalation Toxicology 2:53-67, 1990				
ADD	FH		Morel et al., Acute Pulmonary Vasoconstriction and Thromboxane Release During Protamine Reversal of Heparin Anticoagulation in Awake Sheep, Circulation Research 62:905-915, 1988				
ADD	FI		Morel et al., C5α and Thromboxane Generation Associated with Pulmonary Vaso- and Broncho Constriction during Protamine Reversal of Heparin, Anesthesiology 66:597-604, 1987				
ADD	FJ		Borland et al., A Simultaneous single Breath Measurement of Pulmonary Diffusing Capacity with Nitric Oxide and Carbon Monoxide, Eur. Respir. J. 2:56-63, 1989				
ADD	FK		Altabef et al., Intravenous Nitroglycerin for Uterine Relaxation of an Inverted Uterus, Am. J. Obstet. Gynecol. 166:1237-1238, 1992				
	FL		Oxytocin. Prostaglandins. Ergot Alkaloids. Tocolytic Agents., Chapter 39, pp. 942-945				
	FM		Resnick et al., Evaluation and Medical Management of Urinary Incontinence, Anesthesia pp. 3-6, 1992				
	FN		Zapol et al., Regional Blood Flow During Simulated Diving in the Conscious Weddell Seal, J. Appl. Physiol. 47:968-973, 1979				
ADD	FO		Contractor et al., Development and Evaluation of an Inhalation Aerosol of Nitroglycerin, J. Pharm. Sci. 63:907-911, 1974				
	FP		Jansen et al., The Relaxant Properties in Guinea Pig Airways of S-Nitrosothiols, J. Pharmacology and Experimental Therapeutics 261:154-160, 1992				
EXAMINER <i>Barbara J. Lenz</i>				DATE CONSIDERED 3/20/96			
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ALL	GA		Cremona et al., Endothelium-Derived Relaxing Factor and the Pulmonary Circulation, Lung 169:185-202, 1991				
ALL	GB		Dinh Xuan et al., Acetylcholine and Adenosine Diphosphate Cause Endothelium-dependent Relaxation of Isolated Human Pulmonary Arteries, Eur. Respir. J. 3:633-638, 1990				
ALL	GC		Dinh Xuan et al., Primary Pulmonary Hypertension: Diagnosis, Medical and Surgical Treatment, Respiratory Medicine 84:189-197, 1990				
ALL	GD		Dinh Xuan et al., Non-prostanoid Endothelium-derived Vasoactive Factors, J. International Medical Research 17:305-315, 1989				
ALL	GE		Foubert et al., Safety Guidelines for Use of Nitric Oxide, The Lancet 339:1615-1616, 1992				
ALL	GF		Kreye et al., Comparison of Sodium Nitroprusside and Isoprenaline Aerosols in Histamine-Induced Bronchial Asthma of the Guinea Pig, Naunyn-Schmiedeberg S Arch Pharmacol. 306:203-207, 1979				
ALL	GG		Supplementary European Search Report for corresponding EP application NO. 92902708.4, mailed 19 October 1993				
ALL	GH		PCT Search Report from the corresponding PCT Patent Application No. PCT/US93/06091				
	GI						
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EXAMINER			Aaron J. Levi DATE CONSIDERED 3/20/96				
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HA						
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						YES	NO
HL	WO/93/12068	24/6/93	PCT				
HM	WO/92/17445	28/3/92	PCT				
HN							
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HQ						
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Warren M. Zapol

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(37 CFR 1.98(b))

APPLICANT
Warren M. Zapol et al.FILING DATE
December 9, 1994GROUP
3307

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER							ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
A. L.	AA	5	4	2	7	7	9	7	6/27/95	Frostell et al.	424	434	
	AB												
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							YES	NO
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EXAMINER

David J. Lewis

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